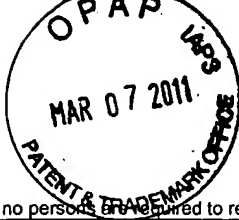


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## PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

32860-001074/US

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

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Application Number

10/589,539

Filed

August 16, 2006

First Named Inventor

Klaus ABRAHAM-FUCHS et al.

Art Unit

8488

Examiner

Edward Winston

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.  
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  
(Form PTO/SB/96)

☒ attorney or agent of record.  
Registration number 34,313

☐ attorney or agent acting under 37 CFR 1.34.  
Registration number if acting under 37 CFR 1.34 \_\_\_\_\_

Signature

Donald J. Daley

Typed or printed name

703-668-8000

Telephone number

March 7, 2011

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.  
Submit multiple forms if more than one signature is required, see below\*.

☐ \*Total of \_\_\_\_\_ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**PATENT**  
32860-001074/US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Klaus ABRAHAM-FUCHS et al. Confirmation No.: 8488  
Application No.: 10/589,539 Examiner: Edward B. Winston, III  
Filing Date: August 16, 2006 Group Art Unit: 3686  
Title: METHOD FOR THE SELECTION OF A PARTICIPANT IN A MEDICAL PROJECT WITH SELECTION CRITERIA FOR PATIENTS  
Attorney Docket: 32860-001074/US

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March 7, 2011

**REASONS FOR PRE-APPEAL REQUEST FOR REVIEW**

Dear Sir:

In response to the Office Action mailed on December 9, 2010 ("Office Action"), Applicants request that the Pre-Appeal Brief Review Panel (hereinafter Panel) review the pending rejections. The Reasons for Pre-Appeal Brief Request for Review are being filed concurrently with the Pre-Appeal Brief Request for Review and a Notice of Appeal.

Claims 1 and 3-14 are pending in the current Application and claims 1 and 3-14 stand rejected. Claims 1 is the sole independent claim.

**Rejections For Which Conference Is Requested**

A Pre-Appeal Brief Conference is respectfully requested to review the rejection to Claims 1 and 3-14 as allegedly being unpatentable over WO 03/040878 to Rao et al. (Rao) in view of US 7,542,911 to Barret et al. (Barret). For the reasons detailed below, withdrawal of the current rejections is requested.

Initially, please see Applicants' statements set out in the Amendment filed June 15, 2010 as reflected by the Applicants' remarks beginning on page 6 with regard to the rejections citing Rao.

Claim 1 is representative and recites:

1. A method for selecting and reporting a potential participant for a medical project with selection criteria for patients, said method comprising:

determining if patient data associated with a patient has changed, the patient data being stored in a data processing system, the data processing system including data associated with a plurality of patients;

checking the patient data with respect to the selection criteria automatically if the determining step determines the patient data has changed;

selecting the patient associated with the patient data as a potential participant if the selection criteria are met; and

reporting the selected patient as a potential participant.

#### **INSUFFICIENCY OF THE REJECTION UNDER § 103(a)**

In rejecting claim 1 the Examiner relies on Rao to disclose the preamble of claim 1 and the checking step of claim 1. See page 3 of the Office Action mailed on December 9, 2010. Further, the Examiner relies on Barret to disclose the determining step of claim 1. See page 4 of the Office Action mailed on December 9, 2010. The Examiner has **not** provided any further references nor has the Examiner pointed to Rao or Barret to disclose the selecting and the reporting steps as recited in claim 1.

In rejecting claims for want of novelty or for obviousness, the examiner must cite the best references at his or her command. When a reference is complex or shows or describes inventions other than that claimed by the applicant, the particular part relied on must be designated as nearly as practicable. The pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified. See 37 C.F.R. § 1.104(c)(2). Emphasis added.

The above rule has been interpreted as the Examiner must state SPECIFICALLY WHERE the cited reference(s) teach the features of the claims. In re Rijckaert, 9 F.3d 1531, 1533, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); see e.g., Ex parte Schricker 56 U.S.P.Q.2D 1723 (BPAI 2000) (requiring cites of column and line number and of Figure numbers).

The current rejection should be withdrawn at least because the Examiner has failed to meet the Examiner's burden of proof in rejecting each and every limitation of each and every claim.

**THE COMBINATION OF RAO AND BARRET DOES NOT DISCLOSE CLAIM 1**

Even assuming *arguendo* that the rejection is sufficient, the combination of Rao and Barret does not disclose at least claim 1.

Rao discloses a strict chronological sequence, namely that the clinical trials brokerage must first obtain a request from a pharmaceutical firm to provide a list of persons, which would meet the special requirements for a clinical trial. For this, the patient data are pulled from a computerized patient record (CPR) of a data warehouse that contains extensive patient records which, in some circumstances, were mined from non-structured hospital records. See at least Rao Abstract.

The patient data are determined at the point of time when the requirement for a list of persons has arrived (is then retrieved). Patient data are always **only** determined once, namely upon request based on the corresponding list by an interested party, that these data are evaluated once, and that a corresponding list is sent to the interested party. See Rao page 3, lines 2-3, page 7, line 20 and page 12, line 7 to page 14, line 14.

Barret relates to synchronizing data between two computing devices, one of which is positioned on the patient while the other one is located at the physician's office. The computing devices include software programs that are capable of modifying a patient record. The software programs also write an

entry into a log should the patient data be modified. See at least Barret Abstract, column 1, lines 1-13 and column 4, lines 44-55.

Rao and Barret do not disclose the steps of “determining if patient data associated with a patient has changed,” “checking the patient data with respect to the selection criteria automatically **if** the determining step determines the patient data has changed,” and “selecting the patient associated with the patient data as a potential participant **if** the selection criteria are met,” as required by claim 1. In short, Rao and Barret do not disclose the steps of selecting a patent for a clinical study based on **a change** in patient data. Further there is not trigger in Rao or Barret to check a patients data against a selection criteria **should the patients data change**.

For at least the reasons described above, Rao and Barret, alone and in combination (assuming *arguendo* that Barret could be combined with Rao, which the Applicants do not admit) do not teach or fairly suggest each and every limitation of claim 1. Because Rao and Barret do not teach or fairly suggest each and every limitation of claim 1, Rao in view of Barret does not render claim 1 obvious. Claims 3-14 are patentable at least by virtue of their dependency from claim 1.

The Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection to claims 1 and 3-14 under 35 U.S.C. § 103(a).

**THE EXAMINER HAS NOT CONSIDERED CLAIM 1 AS A WHOLE**

In rejecting claim 1, the Examiner has at most considered each element of the claim and recited art against each element. The Examiner has not considered the claim as a whole. Further, the Examiner has provided no motivation for triggering a “checking the patient data with respect to the selection criteria” **if** “the determining step determines the patient data has changed,” as required by claim 1. At most, the Examiner has provided a conclusory reason to combine, whereas the Examiner is required to provide “**some articulated reasoning** with some rational underpinning to support the

legal conclusion of obviousness.” KSR, 550 U.S. 398, 82 USPQ2d at 1396 quoting In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). Emphasis added. See also MPEP § 2106, MPEP § 2141.02, MPEP § 2111 - § 2116.01, MPEP § 2141.02 and MPEP § 2143.01 for requirements related obviousness rejections and considering a claim as a whole.

### **CONCLUSION**

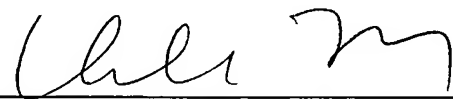
In view of the remarks, reconsideration of the objections and rejections and allowance of each of the pending claims in connection with the present application is earnestly solicited.

Should there be any outstanding matters that need to be resolved in the present application, the Pre-Appeal Brief Review Board is respectfully requested to contact the undersigned at the telephone number. If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKY, & PIERCE, P.L.C.

By

  
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DJD/EPs:lfb

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